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BY FACSIMILE AND FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 99N-0391; Codex Alimentarius Commission: Issues Pertaining to International Guidelines for Vitamin and Mineral Supplements

Ladies/Gentlemen:

On behalf of our client, the National Nutritional Foods Association (NNFA), this letter responds to FDA's request for comments on issues pertaining to the establishment of Codex Alimentarius Commission guidelines for vitamin and mineral supplements (64 Fed. Reg. 17397-99, April 9, 1999).

NNFA is the largest U.S. trade association of suppliers and retailers of dietary supplements. NNFA supports the establishment of Codex guidelines for vitamin and mineral supplements because such guidelines should promote international trade and worldwide consumption of these important health-providing products.

To aid Dr. Elizabeth Yetley, Director of FDA's Office of Special Nutritionals and head of the U.S. Delegation to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) -- which is responsible for developing the subject guidelines – NNFA submits the following comments on the eight specific issues raised in the relevant Federal Register notice, in connection with preparation of the background paper requested by CCNFSDU at its most recent meeting in September, 1998.

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(1) Terminology

NNFA believes that the term "vitamin and mineral supplements" accurately describes the products covered by the existing proposed guidelines.

The Association has previously supported and continues to support Codex coverage of dietary supplements besides those containing vitamins and minerals. In the United States, the term "dietary supplement" is defined by DSHEA to extend beyond vitamins and minerals to include amino acids, herbs and other botanicals, and other dietary substances used to supplement the diet by increasing total dietary intake. This is appropriate, since the term "dietary supplement" conveys the truthful and non-misleading connotation that all of these products supplementally augment overall dietary intake of both nutrients and other beneficial substances.

However, NNFA is concerned that if the term "dietary supplement" is simply substituted for the term "vitamin and mineral supplerments" in the existing Codex guidelines, and such guidelines by virtue of other provisions therein only apply to vitamins and minerals, the guidelines when adopted will not be deemed to cover other dietary supplements, such as amino acids and botanicals.

Thus, NNFA recommends that if the term "dietary supplement" is used in the guidelines, that the definition of dietary supplements be broadened. This could be accomplished by adoption of DSHEA's definition of the term "dietary supplement" or a similar definition. Otherwise, the term "vitamin and mineral supplements" should be retained, and other supplements should be brought under Codex standards either by a future amendment to the guidelines after issuance, or by the development of additional guidelines for the balance of substances in the dietary supplement category.

(2) Purpose & Role

NNFA recommends that all possible legitimate, responsible, and scientifically supportable purposes and roles of dietary supplements be included as the bases for Codex dietary supplement guidelines, such as deficiency disease prevention, nutrient supplementation of restricted diet, nutritional fortification, disease risk reduction, physiological benefit, optimal physical and/or mental performance, and needs of special dietary use.

(3) Approved Nutrients

The Association strongly recommends that neither a positive nor a negative list of dietary supplement ingredients be proposed or approved. Given the wide variation in nutritional requirements and dietary intakes for different nations (and sub-populations, age, and gender groups within those nations), it would be extremely difficult, if not impossible, to assure that any such list is both inclusive and universally valuable as an authoritative reference.

NNFA particularly advises against the development of a list of unapproved (negative) ingredients. Such a list may fail to account for specific individuals, and even entire sub-populations, who may have a nutritional or physiological need to supplement their diet with an ingredient that may not be advisable for the majority of the population. For example, supplemental fluoride is appropriate for children, but not adults, and supplemental iron is appropriate for menstruating women, but not some men.

Virtually all national authorities, as risk managers for public health and safety, have laws and regulations that allow them to restrict or prohibit dietary ingredients that present an unacceptable risk to human health and safety. Such authority is adequate and does not need an international "positive" or "negative" list to be effective.

(4) Maximum Levels

This is perhaps the most critical issue facing CCNFSDU in developing dietary supplement guidelines.

Over many years, the scientific community has continued to evaluate the benefits and safety of nutrients used to supplement the diet, both at recommended daily intake (RDI) levels and at "optimal" levels (which are often considerably higher than RDI levels). Developing maximum allowable levels of ingredients for inclusion in dietary supplements may be theoretically possible. Again, however, maximum allowable levels may fail to account for specific individuals, and even entire sub-populations, who may have a nutritional or physiological need to supplement their diet with a particular dietary ingredient, at levels that are higher than appropriate for the majority of the population. For example, appropriate selenium levels depend on geographical location and diet, and appropriate vitamin D levels depend on weather, diet and lifestyle. There is also the difficulty of arriving at universally accepted numbers for maximum limits.

Moreover, most national authorities, as risk managers for public health and safety, have laws and regulations that permit them to restrict the levels of dietary ingredients present in a dietary supplement, if such ingredients pose a validated and unacceptable risk to human health and safety. Such authority is adequate and does not need internationally developed maximum allowable levels to be effective.

In any event, should CCNFSDU nonetheless decide to adopt any maximum allowable levels for particular dietary supplements, NNFA strongly urges that such decisions be based on sound scientific data and consistent application of sound risk assessment principles. Moreover, the U.S. should emphasize the importance of applying an evidence-based system in this context; rather than one based on policy considerations.

Several primary authoritative sources support a science-based approach to the development of Codex standards. Significantly, the Commission's Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account states: "The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence." Additionally, a number of provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) support the primacy of science in Codex:

Article 2

> 2. "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

Article 3

> 3. "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5."

Article 5

> 1. "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations [such as the Commission]."
>
> 2. "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."
>
> 7. "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

In addition to these primary texts, other sources also support the need for science to be the principal ground for Codex decisionmaking. These sources include the published risk assessment reports of various authorities and recognized experts[1] and the public statements of U.S. governmental bodies.[2] Collectively, these documents provide powerful support for a U.S. position insisting on science-based risk assessment as the foundation of any guidelines for upper safe limits in supplements.

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[1] "Recommended Dietary Allowances" (10th Edition, 1989), Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy of Sciences; "A Scientific Evaluation of the Range of Safe Intakes -- Vitamins and Minerals," Derek Shrimpton, Ph.D., commissioned by the European Health Product Manufacturers Association (EHPM) (1997); "Vitamin & Mineral Safety," John Hathcock, Ph.D., Science Director, Council For Responsible Nutrition, U.S.A. (1997); "A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients," Food And Nutrition Board, Institute of Medicine, National Academy of Sciences (1998).

[2] See the findings in the preamble to the Dietary Supplement Health and Education Act (1994), in the 1998 report of the National Institute of Health, Center for Alternative and Complementary Medicine, and in the 1997 Report of the Presidential Commission on Dietary Supplement Labeling.

(5) Minimal Levels

Guidelines for minimal permissible levels of dietary ingredients for use in dietary supplements should be discussed. Once more, however, given the wide variation in nutritional requirements and dietary intakes for different nations (and sub-populations, age, and gender groups within those nations), it would be difficult, if not impossible, to ensure that such levels are inclusive, scientifically capable of development, and universally valuable as authoritative references.

Such levels may fail to account for specific individuals, and even entire sub-populations, who may have a nutritional or physiological need to supplement their diet with a dietary ingredient at a level greatly in excess of the level determined to be minimally essential for the majority of the population. As examples, appropriate calcium levels depend upon age, diet, and sex, and appropriate folate levels depend on reproductive status and diet.

(6) Purity and Good Manufacturing Practices (GMPs)

Guidelines for manufacturing, packaging, labeling, and storage of dietary supplements should be discussed. They would be helpful in promoting dietary supplement potency and quality. Such guidelines, however, should be based primarily on food manufacturing practices, not on drug manufacturing practices, since the risks associated with poorly manufactured dietary supplements are considerably less than those associated with poorly manufactured drugs (i.e., less adverse pharmacological impact).

NNFA has developed a GMP program for dietary supplements that will be launched shortly. The Association's GMP standards will be provided to FDA as a model of desirable elements for a dietary supplement GMP program that can be considered by CCNFSDU.

(7) Labeling, Warning Statements, and Claims

While recognizing the difficulty inherent in developing guidelines that are universally acceptable, or even appropriate, for the diverse needs of different peoples and nations, NNFA recommends that Codex dietary supplement guidelines incorporate by reference the applicable elements of food labeling ultimately adopted by the Codex Committee on Food Labelling.

(8) Packaging and Marketing

Although again noting the difficulty in developing guidelines that are universally acceptable or appropriate for the diverse needs of different peoples and nations, packaging properties that should be considered for inclusion in dietary supplement guidelines should be those that will (a) retain the product's potency/activity through the expiration/"best before" date; (b) protect children from those products that may pose a health risk or hazard; (c) safeguard the product from environmental contamination; and (d) provide evidence of tampering with the integrity of the product or the package.

NNFA is appreciative of this opportunity to participate in the Codex process for the development of international guidelines for dietary supplements. The Association looks forward to continued collaboration with Dr. Yetley on developing and advocating U.S. positions on these challenging issues.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION

Joe Bassett, President
Michael Q. Ford, Executive Director
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